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10/519,132	09/14/2005	Stephen Strittmatter	23380-602 Natl	7561

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PAUL D. YASGER
ABBOTT LABORATORIES
100 ABBOTT PARK ROAD
DEPT. 377/AP6A
ABBOTT PARK, IL 60064-6008

EXAMINER	
DUTT, ADITI	

ART UNIT	PAPER NUMBER
1649	

NOTIFICATION DATE	DELIVERY MODE
03/07/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

Patents_Abbott_Park@abbott.com
Legal_Patents@abbott.com

Office Action Summary	Application No.	Applicant(s)	
	10/519,132	STRITTMATTER ET AL.	
	Examiner	Art Unit	
	Aditi Dutt	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 November 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) *3-6 and 9-17* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,7 and 8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Note: This Action follows the phone conversation with Gabryleda Ferrari-Dileo on 18 January 2008, regarding potential allowability of the invention. Clarification on the figures and claims with respect to the response to enablement rejection was sought. No response has been received till date.

Status of Claims

1. The amendment filed on 13 November 2007 has been entered into the record and has been fully considered. Claims 1, 2, 7 and 8 are amended. Claims 3-6 and 9-17 are withdrawn by Applicant to non-elected matter.

Election/Restrictions

2. Applicant's response to previous Office Action in the reply filed on 16 July 2007 is acknowledged.

3. Claims 1, 2, 7 and 8, directed to a method for identifying an agent which modulates the binding of an RGM (repulsive guidance molecule) to a Neogenin, comprising detecting and monitoring the binding, are being considered for examination in the instant application.

4. Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

5. Applicant's arguments filed on 13 November 2007, have been fully considered. New grounds of objection and rejection are as follows:

New Objections

Drawings

6. The drawings are objected to because Figure 1E does not clearly relate to the Brief description of the drawings in the instant specification (page 10). Specifically, "Mouse RGM-A-AP and RGM-B-AP" in the Brief description cannot be correlated to "cRGM-AP, mRGM1-AP and mRGM5-AP" in Figure 1E. Additionally, the 3 figures in 1E should be separately labeled (e.g. as "a, b, c", or "i, ii, iii"). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet"

pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

7. In addition to Replacement Sheets containing the corrected drawing figure(s), applicant is required to submit a marked-up copy of each Replacement Sheet including annotations indicating the changes made to the previous version. The marked-up copy must be clearly labeled as "Annotated Sheets" and must be presented in the amendment or remarks section that explains the change(s) to the drawings. See 37 CFR 1.121(d)(1). Failure to timely submit the proposed drawing and marked-up copy will result in the abandonment of the application.

Specification

8. The disclosure is objected to because of the following informalities: The Brief description of the Drawings for Figure 1E should describe all the 3 slides and define the RGM nomenclatures presented in the figure, with relevance to 'A, B' etc.

Appropriate correction is required.

Response to Amendment

Claim rejections/objections maintained

35 U.S.C. 112-second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. The rejection of claims 1, 2, 7 and 8 under 35 U.S.C. 112, second paragraph, are being applied to the amended claims for reasons of record in the Office Action dated 16 July 2007.

10. "A Neogenin":

Applicants argue that para 0082 of the instant application publication describes that a Neogenin corresponds to homologues and variants of Neogenin and that a skilled artisan would know that Neogenin exists in two splice forms, both of which can bind to RGM.

Applicants' arguments are fully considered, but not found to be persuasive. In addition to splice variants, para 0082 also indicates that a Neogenin can comprise homologues that are at least 70% identical with the sequence of Neogenin. In the absence of a sequence identifier for Neogenin, the term "a Neogenin" can encompass numerous sequences. Based on the teaching in the specification, this term would thus be indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is suggested that this could be overcome by stating a specific sequence, preferably with a sequence identifier.

35 U.S.C. 112-first paragraph- Scope of Enablement.

11. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

12. The rejections of claims 1, 2, 7 and 8 are applied to the amended claims for reasons of record in the Office Action dated 16 July 2007.

13. Applicant argues that the specification discloses the binding of chick RGM, mouse RGM A and B to Neogenin (Figure 1). Applicant also provides clarification on the different nomenclatures for RGMs (A, B and C) based on their localization in the chromosomes. Applicants thus believe that sufficient guidance is provided in the specification to identify an agent that will modulate the binding of these molecules with a reasonable amount of success and no undue experimentation.

14. Applicant's arguments directed to the claimed invention have been fully considered but have not been found to be persuasive. As stated in the previous Office Action and supported by the instant specification and relevant art, it is established that RGM A and RGM B binds to Neogenin. On the other hand, neither the instant specification, nor the relevant literature provides any information on the binding characteristics of RGM C to Neogenin. The art teaches mouse RGM C, largely expressed in the striated muscle, as having a genomic organization highly divergent from that of RGMs A or B (Niederkofler et al. J Neurosc 24: 808-818, 2004; page 809, Results, para 1). Since RGM A and

B are typically known for axon repulsion involved in neural growth and development by binding to Neogenin, the role of RGM C cannot be predicted on account of its complete absence from the nervous system (Niederkofler et al. Figure 1C; page 811, col 2, para 1). Besides as stated in the previous Office Action, RGM C is involved in iron metabolism. Based on the above mentioned discrepancies amongst the RGM members, further confounded by the lack of sufficient guidance on the binding properties of all RGM molecules, undue experimentation will be required to identify an agent which modulates the binding of any RGM to Neogenin.

15. Furthermore, Applicant's arguments to support enablement in this regard are confusing. The Office is not clear on the relevance of Applicants' statement on the different nomenclatures for RGMs, other than simply stating the different RGM molecules known in the art. As stated in the "Drawing objections" above, it is not ascertainable as to what does mRGM1 and mRGM5 stand for in Figure E? Are these referring to RGM C and RGM B respectively, especially in light of the nomenclature provided by Applicant in the current response? The Brief description of drawings in the specification also does not present any details in this regard. Applicants have neither provided a specific homologue nor a SEQ ID of RGM for reference. In the absence of such limitations in the claim, the term "a RGM" is broadly interpreted as encompassing any RGM subtype. To further support the Office's contention in this direction, it is stated that in the absence of a specific SEQ ID, "a RGM" could also encompass any homologue or variant that

binds to Neogenin. As in the case of Neogenin stated above, the instant specification describes a RGM to encompass homologues having up to 70% sequence identity with RGM (para 0082). It is well known that certain positions in the sequence are critical to the protein's structure/function relationship, e.g. such as various sites or regions directly involved in binding, activity and in providing the correct three-dimensional spatial orientation of binding and active sites. In the absence of any guidance with regards to the binding domain, what amino acids are required to be conserved, undue experimentation would be required of a skilled artisan.

16. Specifically, proper analysis of the Wands factors was provided in the previous Office Action. Due to the large quantity of experimentation necessary to identify an agent which modulates the binding of any RGM molecule to Neogenin, and monitor such binding, the lack of direction/guidance presented in the specification; the absence of working examples directed to same; the complex nature of the invention; the unpredictability of the binding of all RGM molecules with Neogenin; and the breadth of the claims which fail to recite specific RGM molecules, preferably with specific sequence identifiers, undue experimentation would be required of the skilled artisan to make and/or use the claimed invention.

Conclusion

17. No claims are allowed.

18. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

19. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aditi Dutt whose telephone number is (571) 272-9037. The examiner can normally be reached on Monday through Friday, 9:00 a.m. to 5:00 p.m.

21. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres, can be reached on (571) 272-0867. The

fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

22. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov/. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AD
26 February 2008

JEFFREY STUCKER
SUPERVISORY PATENT EXAMINER